K120524

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May 31, 2012

JUN 21 2012

510(k) Summary

RE: Sphincter of Oddi Manometric System

Summary prepared by:

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Manufaxturer: **Mui Scientific, a Division of H&A Mui Enterprises**
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Trade name: **Sphincter of Oddi Manometric (SOM) System**
Common name: **SOM pump and catheter**
Classification name: **Gastrointestinal motility system**

This 510(k) Summary is for the Sphincter of Oddi Manometric (SOM) System. Indications for Use: When used in conjunction with a computerized motility system for motility studies, this Sphincter of Oddi Manometric System is used to measure the contraction rates of the Sphincter of Oddi within the gastrointestinal system; for research or diagnostic purposes within a clinical setting. The purpose of conducting these diagnostic motility studies is to determine if a patient's pain is caused by Sphincter of Oddi Dysfunction, where the contractions of the Sphincter of Oddi are abnormally high and/or erratic. This dysfunction is most commonly found in patients who have already undergone the removal of their gall bladder. Once diagnosed, the main course of treatment is either medication or sphincterotomy.

This system consists of a water-perfused SOM pump, an air compressor unit, and a Toouli SOM Sleeve catheter. The air compressor unit consists of a compressor motor, a pressure switch, a pressure gauge, and a drying cylinder. When turned on, the motor will compress air into the drying cylinder, which will remove the water by-product from the compression. The pressure switch will turn the motor off at 30psi (as displayed on the pressure gauge), and will restart it when the pressure drops to 10psi. An air hose connects the air compressor unit to the SOM pump to deliver the pressurized air to the SOM pump. The pressurized air will flow through a high pressure gauge (to display the pressure of the supplied compressed air), to a regulator (which will regulate the pressurized air down to 5psi), then a low pressure gauge (to display the pressure of the regulated air), to a water reservoir filled with sterilized irrigation water. The regulated air will push the water out of the water reservoir at a constant

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rate through resistors that will further reduce the water flow rate to 0.18mL/min before it travels through a pressure transducer to the Toouli SOM Sleeve catheter. The proximal end of the Toouli SOM Sleeve catheter has a female luer that connects to the top of the pressure transducer on the SOM pump. The water will flow through the entire length of the Toouli SOM Sleeve catheter to the distal end where a silicone sleeve sensor is located. The Toouli SOM Sleeve catheter is then inserted through the biopsy channel of an endoscope, and then the sleeve sensor is positioned along the Sphincter of Oddi. With the regulated pressurized water flowing through the sleeve sensor at a constant rate, when the sphincter contracts, it will constrict the flow of water through the sleeve sensor, and the pressure change will be transmitted back through the water flow to the pressure transducer on the SOM pump, where the signal will be displayed onto the computer.

We are claiming this system to be substantially equivalent to the following predicates:

- Mui Scientific's pressurized infusion pump
- Mui Scientific's (formerly Dentsleeve Pty) manometric perfusion pump and manometric assemblies
- Arndorfer Inc's pneumo-hydraulic capillary infusion system and ERCP manometric catheters
- Cook Medical's Lehman Sphincter of Oddi Manometric catheter

The SOM pump and air compressor unit is similar to its predicates in that it is driven by a motor to compress the air that gets regulated before it pushes water from a water reservoir through resistors that further reduce the flow rate before passing through the SOM catheter. The Toouli SOM Sleeve catheter is similar to its predicates in that it is long in length and small in diameter, for passing through the biopsy channel of an endoscope, and into the Sphincter of Oddi. The proximal end consists of a female luer, a standard fitting that is compatible with all the predicate water-perfused motility pumps. The number of channels/resistors through which the water is pushed through may vary, and the regulated pressure and flow rates may differ due to the organ being measured, but the concept of pressure transmission along the water medium as a result of a muscle contraction is still the same.

Bench tests were conducted with the Sphincter of Oddi Manometric System, comparing performance data with that of its predicates. With the systems on and perfusing, a specific external force was applied to the distal ends of the SOM catheters to mimic a sphincter contraction. The pressure exerted was shown to equal the pressure measured and transmitted by the SOM catheters. Bench tests were also conducted combining and interchanging the Sphincter of Oddi Manometric System with its predicates, demonstrating that they are compatible and interchangeable.

We intend to market the SOM pump and the Toouli SOM Sleeve catheter as a system. However, other Sphincter of Oddi catheters have been proven to function equally well on the Mui Scientific SOM pump. Likewise, test results have shown that the Toouli SOM Sleeve catheter is able to perform satisfactorily on other water-perfused motility pumps. Therefore, we will also be intending to market the SOM pump and Toouli SOM Sleeve catheter separately, for those doctors wanting to acquire a new SOM pump but continue to use the predicate SOM catheters, and/or for those who already have an existing SOM pump but would like to start using the new Toouli SOM Sleeve catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

Ms. Tammy Mui
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Mui Scientific
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MISSISSAUGA ON L4Z 3L3
CANADA

Re: K120524
Trade/Device Name: Sphincter of Oddi Manometric System
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: May 31, 2012
Received: June 6, 2012

Dear Ms. Mui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120524

Device Name: Sphincter of Oddi Manometric System

Indications For Use:

The Sphincter of Oddi manometric pump and catheter are used in conjunction with a computerized motility system for motility studies, to measure the contraction rates along the gastrointestinal system (specifically the Sphincter of Oddi); for research or diagnostic purposes within a clinical setting.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120524